REMARKS:

Claims 1, 3, 4, 6-14, 16-19 and 23-38 are presented for examination, with claims 1, 14, 17, 19, 23 and 24 having been amended hereby, new claims 25-38 having been added and claims 2, 5, 15 and 20-22 having been cancelled, without prejudice or disclaimer.

Reconsideration is respectfully requested of the objection to the abstract of the disclosure because of the informalities discussed by the Examiner.

More particularly, the abstract of the disclosure has been amended hereby to address the informalities discussed by the Examiner (i.e., the use of the phrases "The present Invention" and "another embodiment of the invention").

Accordingly, it is respectfully submitted that the objection to the abstract of the disclosure because of the informalities discussed by the Examiner has been overcome.

Reconsideration is respectfully requested of the objections to the drawings because of the informalities discussed by the Examiner.

More particularly, in connection with use of the reference character "210" to designate both "vertebrae" and "depression", it is noted that the specification has been amended hereby at page 7, line 5 and page 8, line 2 to designate the two "vertebrae" as 202a and 202b.

In addition, the "Letter With Proposed Drawing Changes" attached hereto includes Figs. 7 and 8 with the reference characters 202a and 202b added.

Further, in connection with use of the reference character "200" to designate both "lobe" and "bone", it is noted that the specification has been amended hereby at page 7, lines 29 and 30 and page 8, line 27 to designate the "bone" as 201.

In addition, the "Letter With Proposed Drawing Changes" attached hereto includes Fig. 6 with the reference character 200 changed to 201.

Further still, in connection with use of the reference characters "20" and "160" in the description but not in Figs. 11A and 11B, it is noted that the "Letter With Proposed Drawing Changes" attached hereto includes Figs. 11A and 11B with the reference characters 20 and 160 (as well as 10) added.

Further still, in connection with use of the reference character "65" in Fig. 4, it is noted that the "Letter With Proposed Drawing Changes" attached hereto includes Fig. 4 with the

reference character 65 changed to 60 (which reference character 60 is referred to in the specification).

Finally, the "Letter With Proposed Drawing Changes" attached hereto includes Fig. 5b with the inner sleeve designated by reference character 20 changed to 22 as suggested by the Examiner.

Accordingly, it is respectfully submitted that the objections to the drawings because of the informalities discussed by the Examiner have been overcome.

Reconsideration is respectfully requested of the rejection of claims 14, 17-19, 23 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More particularly, claim 14 has been amended hereby to more clearly provide antecedent basis for each element recited therein.

Likewise, claims 17 and 19 have been amended hereby to more clearly provide antecedent basis for each element recited therein (of note, claim 18 appears to have been rejected here based solely on its dependence from claim 17).

Further, claim 24 has been amended hereby to more clearly provide antecedent basis for each element recited therein.

Moreover, claim 23 has been amended hereby to recite "The orthopedic implant of claim 1", as suggested by the examiner.

Therefore, it is respectfully submitted that the rejection of claims 14, 17-19, 23 and 24 under 35 U.S.C. 112, second paragraph, has been overcome.

Referring now to the rejection of claims 15 and 22 under 35 U.S.C. 101, as being directed to non-statutory subject matter, it is noted that the cancellation of these claims has rendered their rejection moot. Of note, however, the Examiner's comments have been considered in an effort to expedite prosecution of the present application. More particularly, it is noted that both amended claim 1 and new claim 25 refer to an orthopedic implant "configured to be implanted into a space between a first vertebra and a second vertebra".

Reconsideration is respectfully requested of the rejection of claims 1, 3, 4, 8, 10, 11, 13, 16 and 23 under 35 U.S.C. 102(e) as being anticipated by Michelson (US 2003/0149484).

It is respectfully submitted that applicants do not necessarily concur with the Examiner in

the Examiner's analysis of the claims of the present application and the Michelson disclosure.

Nevertheless, in order to expedite prosecution of the application, claim 1 has been amended hereby to more particularly point out the features of the invention directed to: (a) the implant being provided with a first end and a second end, wherein the first end and the second end are open, wherein the first open end is adapted to contact a first one of the vertebrae, and wherein the second open end is adapted to contact a second one of the vertebrae; and (b) the material from which the sleeve is formed having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

It is believed that these features, as claimed, are neither shown nor suggested by Michelson.

For example, with reference to feature (a) above, it is noted that the implant of Michelson is inserted such that, rather than the open ends themselves, it is the implant section between the open ends which contacts the vertebral bodies (*see*, e.g., Fig. 1 and paragraph 39 (discussing linear insertion into the disc space)).

Moreover, with reference to feature (b) above, it is believed that the implant of Michelson is not described as being formed from a material having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 5 (which had recited this thickness range) from the present Michelson rejection.

Finally, it is noted that claims 3, 4, 8, 10, 11, 13, 16 and 23, which depend either directly or indirectly from claim 1, are submitted to be patentably distinct for at least the same reasons as the claim from which they depend.

Therefore, it is respectfully submitted that the rejection of claims 1, 3, 4, 8, 10, 11, 13, 16 and 23 under 35 U.S.C. 102(e) as being anticipated by Michelson has been overcome.

Reconsideration is respectfully requested of the rejection of claims 1, 3, 8, 10, 11, 13 and 23 under 35 U.S.C. 102(e) as being anticipated by Webb et al. (6,503,279).

It is respectfully submitted that applicants do not necessarily concur with the Examiner in the Examiner's analysis of the claims of the present application and the Webb et al. disclosure.

Nevertheless, in order to expedite prosecution of the application, claim 1 has been

amended hereby to more particularly point out the feature of the invention directed to the material from which the sleeve is formed having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

It is believed that this feature, as claimed, is neither shown nor suggested by Webb et al.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 5 (which had recited this thickness range) from the present Webb et al. rejection.

Finally, it is noted that claims 3, 8, 10, 11, 13, 16 and 23, which depend either directly or indirectly from claim 1, are submitted to be patentably distinct for at least the same reasons as the claim from which they depend.

Therefore, it is respectfully submitted that the rejection of claims 1, 3, 8, 10, 11, 13, 16 and 23 under 35 U.S.C. 102(e) as being anticipated by Webb et al. has been overcome.

Reconsideration is respectfully requested of the rejection of claims 1, 3, 4, 8, 10, 12, 13 and 23 under 35 U.S.C. 102(b) as being anticipated by Knothe et al. (6,143,031).

It is respectfully submitted that applicants do not necessarily concur with the Examiner in the Examiner's analysis of the claims of the present application and the Knothe et al. disclosure.

Nevertheless, in order to expedite prosecution of the application, claim 1 has been amended hereby to more particularly point out the features of the invention directed to: (a) the implant being provided with a first end and a second end, wherein the first end and the second end are open, wherein the first open end is adapted to contact a first one of the vertebrae, and wherein the second open end is adapted to contact a second one of the vertebrae; and (b) the material from which the sleeve is formed having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

It is believed that these features, as claimed, are neither shown nor suggested by Knothe et al.

For example, with reference to feature (a) above, it is noted that the implant of Knothe et al. is inserted such that, rather than the open ends themselves, it is the implant section between the open ends which contacts the vertebral bodies (*see*, e.g., Figs. 1 and 2 and Col. 2, lines 35-41 ("The upper and the lower bone-contact faces 3 and 4 are elastically compressible towards the interior space 6...")).

Moreover, with reference to feature (b) above, it is believed that the implant of Knothe et al. is not described as being formed from a material having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 5 (which had recited this thickness range) from the present Knothe et al. rejection.

Finally, it is noted that claims 3, 4, 8, 10, 12, 13 and 23, which depend either directly or indirectly from claim 1, are submitted to be patentably distinct for at least the same reasons as the claim from which they depend.

Therefore, it is respectfully submitted that the rejection of claims 1, 3, 4, 8, 10, 12, 13 and 23 under 35 U.S.C. 102(b) as being anticipated by Knothe et al. has been overcome.

Reconsideration is respectfully requested of the rejection of claims 1, 3, 8, 10 and 12 under 35 U.S.C. 102(e) as being anticipated by Weiland et al. (6,371,987).

It is respectfully submitted that applicants do not necessarily concur with the Examiner in the Examiner's analysis of the claims of the present application and the Weiland et al. disclosure.

Nevertheless, in order to expedite prosecution of the application, claim 1 has been amended hereby to more particularly point out the features of the invention directed to: (a) the implant being provided with a first end and a second end, wherein the first end and the second end are open, wherein the first open end is adapted to contact a first one of the vertebrae, and wherein the second open end is adapted to contact a second one of the vertebrae; and (b) the material from which the sleeve is formed having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

It is believed that these features, as claimed, are neither shown nor suggested by Weiland et al.

For example, with reference to feature (a) above, it is noted that the implant of Weiland et al. is inserted such that, rather than the open ends themselves, it is the implant section between the open ends which contacts the vertebral bodies (*see*, e.g., Figs. 5 and 6 and Col. 4, lines 18-31 ("the implant can be inserted in the direction of the longitudinal axis of the connecting portion 1 into the intermediate space between the vertebrae 8 and 9...")).

Moreover, with reference to feature (b) above, it is believed that the implant of Weiland

et al. is not described as being formed from a material having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 5 (which had recited this thickness range) from the present Weiland et al. rejection.

Finally, it is noted that claims 3, 8, 10 and 12, which depend either directly or indirectly from claim 1, are submitted to be patentably distinct for at least the same reasons as the claim from which they depend.

Therefore, it is respectfully submitted that the rejection of claims 1, 3, 8, 10 and 12 under 35 U.S.C. 102(e) as being anticipated by Weiland et al. has been overcome.

Reconsideration is respectfully requested of the rejection of claims 1, 3, 4, 6-8, 10, 12, 13 and 23 under 35 U.S.C. 102(e) as being anticipated by Biscup (6,245,108).

It is respectfully submitted that applicants do not necessarily concur with the Examiner in the Examiner's analysis of the claims of the present application and the Biscup disclosure.

Nevertheless, in order to expedite prosecution of the application, claim 1 has been amended hereby to more particularly point out the feature of the invention directed to the material from which the sleeve is formed having a thickness dimension in the size range of about 0.5 mm to about 3.0 mm.

It is believed that this feature, as claimed, is neither shown nor suggested by Biscup.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 5 (which had recited this thickness range) from the present Biscup rejection.

Finally, it is noted that claims 3, 4, 6-8, 10, 12, 13 and 23, which depend either directly or indirectly from claim 1, are submitted to be patentably distinct for at least the same reasons as the claim from which they depend.

Therefore, it is respectfully submitted that the rejection of claims 1, 3, 4, 6-8, 10, 12, 13 and 23 under 35 U.S.C. 102(e) as being anticipated by Biscup has been overcome.

Reconsideration is respectfully requested of the rejection of claims 1, 3, 9-11, 14, 17-19 and 24 under 35 U.S.C. 102(e) as being anticipated by Lemperle et al. (6,391,059).

It is respectfully submitted that applicants do not necessarily concur with the Examiner in

the Examiner's analysis of the claims of the present application and the Lemperle et al. disclosure.

Nevertheless, in order to expedite prosecution of the application, claim 1 has been amended hereby to more particularly point out the feature of the invention directed to an orthopedic implant configured to be implanted into a space between a first vertebra and a second vertebra, wherein the implant is provided with a first open end and a second open end, wherein the first open end is adapted to contact the first one of the vertebrae, wherein the second open end is adapted to contact the second one of the vertebrae, and wherein the implant bears a load between the first one of the vertebrae and the second one of the vertebrae.

Further, claim 17 has been amended hereby to more particularly point out the feature of the invention directed to a method of providing an orthopedic implant, wherein a sleeve is constructed of a sheet formed of titanium.

Further still, claim 24 has been amended hereby to more particularly point out the feature of the invention directed to a method of providing an orthopedic implant, wherein a sleeve is constructed of a loop formed of titanium.

It is believed that these features, as claimed, are neither shown nor suggested by Lemperle et al.

For example, with reference to claim 1, it is believed that the flexible "membrane" of Lemperle et al. is not suited to form two open ends to contact two vertebrae and to bear a load therebetween.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 22 (which had recited use of the implant in the space between two vertebrae) from the present Lemperle et al. rejection.

Moreover, with reference to claims 17 and 24, it is believed that the flexible "membrane" of Lemperle et al. is not described as being formed from titanium (*see*, e.g., Col. 5, lines 54-56 ("The implant further includes a plurality of apertures disposed in the substantially planar sheet of non-metallic base material").

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 4 (which recites that the biocompatible material is titanium) from the present Lemperle et al. rejection.

Finally, it is noted that claims 3, 9-11, 14, 18 and 19, which depend either directly or indirectly from claims 1 or 17, are submitted to be patentably distinct for at least the same reasons as the claim from which they depend.

Therefore, it is respectfully submitted that the rejection of claims 1, 3, 9-11, 14, 17-19 and 24 under 35 U.S.C. 102(e) as being anticipated by Lemperle et al. has been overcome.

Referring now to new claims 25-38, in order to expedite prosecution of the application, applicants would like to take a few moments to point out to the Examiner certain features of these claims which render them patentably distinct over the cited references.

More particularly, with regard to Michelson, it is noted that claim 25 (as well as claims 26-38 via dependence thereto), recites that: (a) the implant is provided with a first end and a second end, wherein the first end and the second end are open, wherein the first open end is adapted to contact a first one of the vertebrae, and wherein the second open end is adapted to contact a second one of the vertebrae; and (b) the implant has corrugations extending radially outward around an axis extending from the first one of the vertebrae to the second one of the vertebrae.

It is believed that these features, as claimed, are neither shown nor suggested by Michelson.

For example, with reference to feature (a) above, it is noted that the implant of Michelson is inserted such that, rather than the open ends themselves, it is the implant section between the open ends which contacts the vertebral bodies (*see*, e.g., Fig. 1 and paragraph 39 (discussing linear insertion into the disc space)).

In addition, with reference to feature (b) above, it is noted that to the extent that Michelson could be said to provide any corrugation, such corrugation would extend outward from an axis perpendicular to the vertebral bodies, and not from the axis extending from the first one of the vertebrae to the second one of the vertebrae.

Further, with regard to Webb et al., it is noted that claim 25 (as well as claims 26-38 via dependence thereto), recites that the biocompatible material is titanium.

It is believed that this feature, as claimed, is neither shown nor suggested by Webb et al.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 4 (which recites that the biocompatible material is

titanium) from the Webb et al. rejection made in the October 3, 2003 Office Action.

Further still, with regard to Knothe et al., it is noted that claim 25 (as well as claims 26-38 via dependence thereto), recites that: (a) the implant is provided with a first end and a second end, wherein the first end and the second end are open, wherein the first open end is adapted to contact a first one of the vertebrae, and wherein the second open end is adapted to contact a second one of the vertebrae; and (b) the implant has corrugations extending radially outward around an axis extending from the first one of the vertebrae to the second one of the vertebrae.

It is believed that these features, as claimed, are neither shown nor suggested by Knothe et al.

For example, with reference to feature (a) above, it is noted that the implant of Knothe et al. is inserted such that, rather than the open ends themselves, it is the implant section between the open ends which contacts the vertebral bodies (*see*, e.g., Figs. 1 and 2 and Col. 2, lines 35-41 ("The upper and the lower bone-contact faces 3 and 4 are elastically compressible towards the interior space 6...")).

In addition, with reference to feature (b) above, it is noted that to the extent that Knothe et al. could be said to provide any corrugation, such corrugation would extend outward from an axis perpendicular to the vertebral bodies, and not from the axis extending from the first one of the vertebrae to the second one of the vertebrae.

Further still, with regard to Weiland et al., it is noted that claim 25 (as well as claims 26-38 via dependence thereto), recites that the biocompatible material is titanium.

It is believed that this feature, as claimed, is neither shown nor suggested by Weiland et al.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 4 (which recites that the biocompatible material is titanium) from the Weiland et al. rejection made in the October 3, 2003 Office Action.

Further still, with regard to Biscup, it is noted that claim 25 (as well as claims 26-38 via dependence thereto), recites that the implant has corrugations extending radially outward around an axis extending from the first one of the vertebrae to the second one of the vertebrae.

It is believed that this feature, as claimed, is neither shown nor suggested by Biscup.

For example, it is noted that to the extent that Biscup could be said to provide any

corrugation, such corrugation (i.e., rigid structures 80) would be in line with the axis extending between the vertebral bodies, and not extending radially outward therefrom.

Further still, with regard to Lemperle et al., it is noted that claim 25 (as well as claims 26-38 via dependence thereto), recites that: (a) the orthopedic implant is configured to be implanted into a space between a first vertebra and a second vertebra, wherein the implant is provided with a first open end and a second open end, wherein the first open end is adapted to contact the first one of the vertebrae, wherein the second open end is adapted to contact the second one of the vertebrae, wherein the implant bears a load between the first one of the vertebrae and the second one of the vertebrae and wherein the implant has corrugations extending radially outward around an axis extending from the first one of the vertebrae to the second one of the vertebrae; and (b) the biocompatible material is titanium.

It is believed that these features, as claimed, are neither shown nor suggested by Lemperle et al.

For example, with reference to feature (a) above, it is believed that the flexible "membrane" of Lemperle et al. is not suited to form two open ends to contact two vertebrae and to bear a load therebetween.

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 22 (which had recited use of the implant in the space between two vertebrae) from the Lemperle et al. rejection made in the October 3, 2003 Office Action.

In addition, it is believed that the claimed corrugated configuration is not shown or suggested by Lemperle et al.

Moreover, with reference to feature (b) above, it is believed that the flexible "membrane" of Lemperle et al. is not described as being formed from titanium (*see*, e.g., Col. 5, lines 54-56 ("The implant further includes a plurality of apertures disposed in the substantially planar sheet of non-metallic base material").

In fact, it is respectfully submitted that the Examiner herself has actually implicitly acknowledged this by excluding original claim 4 (which recites that the biocompatible material is titanium) from the Lemperle et al. rejection made in the October 3, 2003 Office Action.

Accordingly, it is respectfully submitted that each objection and rejection raised by the

Examiner in the October 3, 2003 Office Action has been overcome and that the above-identified application is now in condition for allowance.

Finally, it is noted that this Amendment is fully supported by the originally filed application and thus, no new matter has been added. For this reason, the Amendment should be entered.

More particularly, support for the amendments to the abstract is found in the abstract, as filed; and throughout the specification.

Further, support for the amendments to the specification at pages 7 and 8 regarding the vertebrae is found in the specification at pages 7 and 8, as filed; in Figs. 7 and 8, as filed; and throughout the specification.

Further still, support for the amendments to the specification at pages 7 and 8 regarding the bone is found in the specification at pages 7 and 8, as filed; in Fig. 6, as filed; and throughout the specification.

Further still, support for the amendment to claim 1 is found in claims 1, 2, 5 and 22, as filed; at page 3, lines 2-4, page 4, lines 4-6, page 7, lines 4-7, and page 9, lines 5-9; in Figs. 7 and 8; and throughout the specification.

Further still, support for the amendment to claim 14 is found in claims 1 and 14, as filed; at page 8, lines 5-9; in Figs. 9 and 10; and throughout the specification.

Further still, support for the amendment to claim 17 is found in claims 4 and 17, as filed; at page 3, lines 4-6; and throughout the specification.

Further still, support for the amendment to claim 19 is found in claims 17-19, as filed; at page 8, lines 5-9; in Figs. 9 and 10; and throughout the specification.

Further still, support for the amendment to claim 23 is found in claims 1, 22 and 23, as filed; at page 3, lines 9 and 10; and throughout the specification.

Further still, support for the amendment to claim 24 is found in claims 4 and 24, as filed; at page 3, lines 4-6; and throughout the specification.

Further still, support for new claim 25 is found in claims 1, 2, 5 and 22, as filed; at page 3, lines 2-4, page 4, lines 4-6, page 7, lines 4-7, and page 9, lines 5-9; in Figs. 7 and 8; and throughout the specification.

Further still, support for new claim 26 is found in claims 1 and 3, as filed; at page 3, line

29 to page 4, line 3; in Figs. 12-17; and throughout the specification.

Further still, support for new claim 27 is found in claims 1 and 5, as filed; at page 4, lines 4-6; and throughout the specification.

Further still, support for new claim 28 is found in claims 1 and 6, as filed; at page 3, line 29 to page 4, line 3; in Figs. 12-17; and throughout the specification.

Further still, support for new claim 29 is found in claims 1 and 7, as filed; at page 3, line 29 to page 4, line 3; in Figs. 12-17; and throughout the specification.

Further still, support for new claim 30 is found in claims 1 and 8, as filed; at page 2, lines 19-24; and throughout the specification.

Further still, support for new claim 31 is found in claims 1 and 9, as filed; at page 2, lines 13-18; and throughout the specification.

Further still, support for new claim 32 is found in claims 1 and 10, as filed; at page 2, lines 25-28; and throughout the specification.

Further still, support for new claim 33 is found in claims 1 and 11, as filed; at page 2, lines 19-24; and throughout the specification.

Further still, support for new claim 34 is found in claims 1 and 12, as filed; at page 2, lines 19-24; and throughout the specification.

Further still, support for new claim 35 is found in claims 1 and 13, as filed; at page 3, lines 7-12, page 8, lines 18-20; and throughout the specification.

Further still, support for new claim 36 is found in claims 1 and 14, as filed; at page 8, lines 5-9; Figs. 9 and 10; and throughout the specification.

Further still, support for new claim 37 is found in claims 1 and 16, as filed; at page 8, lines 10-13; Figs. 5a, 5b and 5c; and throughout the specification.

Further still, support for new claim 38 is found in claims 1, 22 and 23, as filed; at page 3, lines 7-12, page 8, lines 18-20; and throughout the specification.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,
GREENBERG TRAURIG

Dated: December 30, 2003

By: _____
Matthew B. Tropper
Registration No. 37,457

Mailing Address:
GREENBERG TRAURIG
885 Third Avenue
New York, New York 10022
(212) 801-2100
Facsimile: (212) 688-2449

Exhibit A

--~~The present invention is directed to an~~ An orthopedic implant that is comprised of a corrugated foraminous sleeve. The sleeve is formed with alternating grooves and ridges, referred to herein as lobes and depressions. The corrugated sleeve may be formed from a sheet provided with openings (foramina), which is then corrugated to impart the lobes and depressions. The sheet may then be enclosed in a loop, such as a circular shape, elliptical shape, or any other shape contemplated by the skilled artisan, to form a corrugated cage that may be used as an orthopedic implant. ~~In another embodiment of the invention, the~~ The corrugated foraminous implant ~~is~~ may be formed from a pre-formed foraminous loop, such as a loop having a circular shape, an elliptical shape, or any other shape contemplated by a skilled artisan. The loop is processed to impart the corrugated nature of the invention, as manifested in the lobes and depressions of the implant. The preformed loop can be an endless loop having no discernible point where two ends are joined.--